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| 10/533,522 | 05/02/2005 | Istvan Hudak | 9007-1011 | 1625 |
| 466 | 7590 | 07/09/2009 | EXAMINER | |
| YOUNG & THOMPSON | | | ROGERS, JAMES WILLIAM | |
| 209 Madison Street | | | | |
| Suite 500 | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/533,522 | HUDAK, ISTVAN | |
| | Examiner | Art Unit | |
| | JAMES W. ROGERS | 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 13 March 2009.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 32,36-46,50-57 and 59-65 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 32,36-46,50-57 and 59-65 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

 1. Certified copies of the priority documents have been received.

 2. Certified copies of the priority documents have been received in Application No. _____.

 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Applicants amendments to the claims filed 03/13/2009 have been entered.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32,36,43-46,50,57,59-61 and 64-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Garabaldi et al. (US 6,364,823 B1), this new rejection was necessitated by applicants amendments to the claims.

Garabaldi teaches compositions for treating vascular defects such as aneurysms and includes a mixture of biocompatible polymers such as polyurethane dissolved in biocompatible solvents that included DMSO and ethanol. See abstract, col 3 lin 56-col4 lin 4, col 11 lin 19-29 and claims 1,2,11-16. The polymer precipitates at the vascular defect as the solvent dissipates into the body. The composition could further contain a radio-opaque agent including tantalum powder. The composition was delivered by catheter, it is noted by the examiner that any conceivable injectable composition would have to be contained in some type of kit before use and applicants have not particularly claimed any physical limitations on the type of kit that would distinguish it from the prior art.

Claims 32,36,44-46,50,59-61 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al. (US 6,261,583 B1), this new rejection was necessitated by applicants amendments to the claims.

Dunn teaches implantable compositions for delivery of bioactive agents, the composition contained a thermoplastic polymer including polyurethane that is at least

partially dissolved in a biocompatible solvent, preferably DMSO. See abstract, col 1 lin 36-43, col 2 lin 11-17, col 5 lin 55-col 6 lin 2, col 32-33 and claims. In use the implant is flowable and becomes a solidified mass at the site when it becomes infused with body fluid and the solvent is dispersed. See col 1 lin 43-50, col 2 lin 25-34, col 4 lin 43-52. The delivery site for the in-situ formed implant included tissue defects such as void spaces in a periodontal pocket or surgical incision. See col 2 lin 49-55. Regarding the intended use recitations found within all the independent claims that the composition is used to fill or short circuit a vascular cavity, since the composition described by Dunn is within the scope of applicants claimed composition it will be able to perform the same intended use. The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 32,36-46,50-57,59-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garibaldi et al. (US 6,364,823 B1) in view of Porter (US 2002/0165583 A1), this new rejection was necessitated by applicants amendments to the claims.

Garibaldi is disclosed above. Garabaldi does not describe a viscosity within the claimed range for dependent claims 40,41,54-55,62 and 63, however the reference claims a viscosity (30 centipose to 1500 centipose) that overlaps applicants claimed range. Adjusting the viscosity of an embolic composition is no more than routine experimentation in order to form a composition with the desired properties. For instance Garabaldi discloses that if the viscosity is too low it will not be able to suspend paramagnetic particles and if the composition is too viscous it will be incapable of delivering the composition by catheter. Thus it would have been routine and obvious for one of ordinary skill in the art to adjust the compositions viscosity in order to achieve the desired effects and one of ordinary skill in the art would have a reasonable expectation of success in finding the optimum value.

Garabaldi while disclosing the use of polyurethanes in the embolic composition is silent on the specific types or features of those polyurethanes, thus the reference does not disclose the features set forth in dependent claims 37-39,42 and 51-53.

Porter is described in the previous office actions filed 11/14/2007, 05/23/2008, 12/15/2008 and further below. As noted previously Porter describes a prepolymer that forms a polyurethane in situ when delivered to the vascular site, the polyurethane is formed from a polyether polyol (polyoxyethylene, polyoxypropylene and the like) and an isocyanate including 4,4-diphenylmethanediisocyanate. See [0050],[0059]-[0061]. While Porter describes the use of prepolymers that form the complete polyurethane in-situ it would have been obvious to one of ordinary skill in the art that the complete polyurethane (not prepolymer) could be used in the composition of Garabaldi since that

reference details a procedure of solvating polymers such as polyurethanes with biocompatible solvents. The references do not describe a polymer within applicants claimed range for dependent claims 42 and 56, however it would have been obvious to one of ordinary skill in the art to vary the concentrations of diisocyanate and polyol as well as the reaction conditions to form a polyurethane mixture with a polydispersity index that achieves the desired properties. Regarding claim 52, it also would be obvious from the disclosure of Porter that the main diol component would comprise a very high concentration of polyether. This is because the polyurethane made by Porter would contain mostly polyether polyol, which has a much higher molecular weight than the diisocyanates that form the polyurethane linkers. The polymer can further comprise 1 to 50% of another polymer including hydroxyl or amine terminated compounds, further allowing one of ordinary skill in the art to adjust the amount of polyol in the backbone.

It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the embolic composition disclosed in Garabaldi, specifically the disclosed polyurethanes and substitute the specific polyurethanes disclosed within Porter. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of

conventional components, specifically polyurethanes used in embolic compositions. It therefore follows that the instant claims define *prime facie* obvious subject matter.

Response to Arguments

Applicant's arguments filed 03/13/2009 have been fully considered but they are not persuasive. 46,50-53,56-57,59 and 61-65 rejected under 35 U.S.C. 102(e) as being anticipated by Porter (US 2002/0165583 A1), for the reasons set forth in the previous office actions filed 11/14/2007 and 12/15/2008.

Applicants assert that Porter fails to describe a solid polyurethane that is dissolved in a solvent. Instead applicants argue Porter only refers to polyurethane in terms of its prepolymer components which are liquid when they are added to the embolic composition and only form polyurethanes *in-situ*. Applicants further contend that a prepolymer is not a polymer

First it is noted by the examiner that a prepolymer is still a polymer. Applicants have not limited the MW of the polyurethane (PU) at least within the independent claims to exclude a small polymer or even an oligomer of urethane such as the prepolymers of Porter. Secondly the claims rejected above are drawn to a composition or kit containing PU and solvent, the claims rejected are not drawn to a process of making the composition. Thus whether or not PU was solid before being dissolved in the composition is of little concern since the composition of Porter is within applicants claimed scope. Essentially the limitation that the polyurethane is a solid before being added to the composition is a product by process type of limitation. "[E]ven though

product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claims 32,36,43-46,50,56-57,59-62 and 65-65 rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al. (US 5,702,361), for the reasons set forth in the previous office action filed 12/15/2008.

Applicants assert that Evans fails to disclose dissolving a solid PU polymer that is dissolved in a solvent.

The examiner respectfully disagrees. Clearly Evans teaches two different embodiments, in the first a polymer composition is described and the second embodiment teaches a prepolymer composition, if the polymer was used it was dissolved in the solvent, since it was dissolved in solvent the polymer was inherently solid.

Claims 32,36,43-46,50,56-57,59-62 and 65-65 rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al. (US 6,342,202), for the reasons set forth in the previous office action filed 12/15/2008.

Applicants assert that urethane carbonate copolymers are different than their claimed PU polymers and as evidence submit PU and urethane/carbonate copolymers are described separately in Table 1 of Evans, thus applicants contend they have

different physical properties. Applicants further argue that the claims recite PU is obtained by polyaddition reactions of diols and diisocyanates, which would exclude carbonate/urethane copolymers. Applicants further assert that there is no suggestion that PU is dissolved in a solvent and table 1 shows that PU does not dissolve in DMSO which is contrary to their own invention.

The examiner respectfully disagrees. Firstly the claims recite a composition containing PU; the claims do require that PU is a homopolymer, thus a copolymer containing repeat urethane units is not excluded from the scope of the claims. Regarding the assertion that urethane/carbonate copolymers are excluded by the claimed method to make them, the claims rejected above are not drawn to a method of making PU, but to a method to make a composition, the composition itself and a kit comprising the composition, thus this argument is moot. Applicants are correct in that table 1 shows that a specific PU was insoluble in DMSO, however this is just one example and other types of solvents were contemplated within the disclosure of Evans. The examples within Evans were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the invention. Clearly Evans teaches that the biocompatible polymer includes PU and the biocompatible solvent is selected so that the biocompatible polymer is soluble within it. See col 3 lin 66-col 4 lin 5.

Claims 32,36-46,50-57,59-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter (US 2002/0165583 A1), for the reasons set forth in the previous office actions filed 11/14/2007 and 12/15/2008.

Applicants assert that Porter does not disclose or suggest utilizing a solid PU which is then dissolved in solvent. Applicants further contend that Porter teaches away from their claimed invention because the solutions of Porter contain a crosslinked polymer.

The relevance of these assertions is unclear. At paragraph [0087] Porter discusses an embodiment in which a polymer is dissolved in solvent and further discusses that these types of compositions are known in the prior art as previously discussed within the reference. Porter did recite the use of polyurethanes as a material useful in embolization of a vascular site, while the previous disclosure discussed prepolymers of polyurethane since the passage at [0087] includes all compositions and polymers discussed previously it would have been obvious to one of ordinary skill that the polyurethane formed from the prepolymers could be used as the dissolved polymer. Thus from the complete disclosure of Porter one of ordinary skill in the art would have had a reasonable expectation of success in dissolving polyurethane to form an embolic composition. Contrary to applicants assertion that the composition of Porter must contain a crosslinker, paragraph [0087] only describes a polymer dissolved in solvent, a stream of air was used to precipitate the polymer out of solution, a crosslinker was not mentioned.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618